Final Report to Congress
Endangered Species Act Implementation in
Pesticide Evaluation Programs

December 2016

Prepared by the
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National Marine Fisheries Service
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Purpose of this Report to Congress

The National Academy of Sciences' (NAS) National Research Council (NRC) report, entitled "*Assessing Risks to Endangered and Threatened Species from Pesticides*" (NAS NRC report) was released on April 30, 2013. The NAS NRC report contained recommendations on scientific and technical issues related to pesticide consultations under the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

This final *Report to Congress* updates the November, 2014, interim *Report to Congress* that described the approaches and actions taken by the Environmental Protection Agency (EPA), the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) (the Agencies) to respond to the NAS NRC report recommendations. In addition, as directed by the Agricultural Act of 2014 (P.L. 113-79), this final report informs Congress of actions that have been, and will be taken, to establish that: (1) the Agencies utilize the best available science; (2) Reasonable and Prudent Alternatives (RPA) will be technologically and economically feasible; (3) Reasonable and Prudent Measures (RPM) will be necessary and appropriate; and (4) the Agencies will ensure public participation and transparency in developing RPAs and RPMs.

This final report, as directed, also updates the study and report required by subsection (b) and (c) of section 1010 of Public Law 100-478 (7 U.S.C. 136a note). Section 1010 provides direction to the EPA, United States Department of Agriculture (USDA), and Department of the Interior to educate persons engaged in agricultural food and fiber commodity production to educate and provide opportunities to engage in agricultural food and fiber commodity production in EPA's pesticide labeling program as it relates to compliance with the ESA (16 U.S.C. 1531 et seq.).

Legal Construct and Litigation Status of the Agencies' Pesticides Work

Legal Construct

The Agencies each have different legal responsibilities that we must integrate as we jointly implement a process and scientific methods to complete successful pesticide consultations. Below is a description of the pertinent legal requirements as it relates to the development of the pesticide consultations.

EPA – EPA regulates the distribution, sale, and use of pesticides under FIFRA. Under section 3 of FIFRA, subject to limited exceptions, a pesticide must be registered by the EPA prior to its distribution or sale. Before EPA may register a pesticide under FIFRA, the applicant must show,

among other things that using the pesticide according to specifications on the label "will not generally cause unreasonable adverse effects on the environment."[1] If EPA concludes the pesticide, together with its accompanying labeling and any terms and conditions will not cause unreasonable adverse effects on the environment, EPA grants the registration, and the labeling provisions approved by EPA become the enforceable instructions for the use of a pesticide product. As part of the regulatory decision making under FIFRA, EPA also considers the benefits of the pesticide and the potential impact to growers. Post-registration, EPA reviews and re-evaluates a pesticide every 15 years as part of its registration review program to determine whether it continues to meet the FIFRA registration standard. EPA is using the registration review process to address ESA obligations for pesticide registrations through the development of nationwide effects determinations.

NMFS and USFWS – Under section 7(a)(2) of the ESA, all Federal action agencies have responsibility to insure that any action authorized, funded, or carried out by that agency is not likely to jeopardize the continued existence of any Federally listed endangered or threatened species (ESA-listed species), or result in the destruction or adverse modification of designated critical habitat.

ESA section 7(a)(2) – requires that Federal action agencies initiate "consultation" with NMFS and/or USFWS on actions that "may affect" ESA-listed species or designated critical habitat. NMFS and/or USFWS conclude a formal consultation by issuing a Biological Opinion that addresses the proposed Federal agency action considered during consultation. NMFS and/or USFWS determine whether the proposed action assessed in the Biological Opinion is likely to jeopardize the continued existence of an ESA-listed species, or adversely modify/destroy designated critical habitat. If NMFS and/or USFWS determine from their assessment that a proposed action is likely to jeopardize the continued existence of the species, or adversely modify/destroy designated critical habitat, they must provide the Federal action agency with draft RPAs.

If NMFS and/or USFWS conclude that take of the species (*i.e.*, harass, harm[2], pursue, hunt, shoot, wound, kill, trap, capture, or collect any threatened or endangered species) does not violate ESA section 7(a)(2), NMFS and USFWS provide the Federal agency with an incidental take statement. The incidental take statement identifies the amount or extent of incidental take

[1] FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

[2] Harm is further defined in 50 CFR Part 222

exempted for the proposed action, along with mandated RPMs and terms and conditions to minimize the impact of the take.

The USDA, while it does not have a formal role in the ESA consultation process between EPA (the Federal action agency), NMFS and USFWS, does play an important role in providing the Agencies pesticide use and usage data, and information on agricultural production practices when requested. USDA's National Agricultural Statistics Service has also provided assistance on the appropriate use of the Cropland Data Layer and other geospatial information related to the location of agricultural crops.

Litigation Status of the Pesticide Consultations

The Agencies have worked to align existing settlements and lawsuits so that we can focus on national-level consultations for all ESA-listed species, rather than focus on single species, or a small subset of species in smaller geographical areas that were the initial focus of the ESA-related litigation. Based on recent settlement agreements as part of ongoing litigation against EPA, NMFS, and USFWS (i.e., Northwest Center for Alternatives to Pesticides v. EPA, Northwest Center for Alternatives to Pesticides v. NMFS, Center for Biological Diversity v. EPA and, Center for Biological Diversity v. USFWS), the Agencies agreed to coordinate completion of nationwide consultations for nine pesticides: carbaryl, chlorpyrifos, diazinon, malathion, methomyl, glyphosate, atrazine, propazine and simazine. The dates provided for completion of consultation in those settlements are December, 2017 for chlorpyrifos, diazinon, and malathion, December, 2018 for carbaryl and methomyl, and December 2022 for glyphosate, atrazine, simazine and propazine. Further information on ESA-related litigation and associated settlement agreements can be found at the following link: http://www.epa.gov/endangered-species/endangered-species-litigation-and-associated-pesticide-limitations. The Agencies are also working on out-year planning for further pesticide consultations beyond 2022.

Although the Agencies have been able to reach agreement with existing litigants to allow the Agencies to focus their work on implementing the NAS NRC report recommendations through the nationwide consultations identified above, EPA is now facing several new legal challenges to its approval of new active ingredients from these and other litigants. Unfortunately, these new legal challenges will continue to divert limited resources from the Agencies' current focus on existing pesticides that potentially pose broader risk concerns for ESA-listed species and designated critical habitat than the proposed new active ingredients.

Issues Raised in the Agricultural Act of 2014 Related to Pesticides Consultations

On February 7, 2014, President Obama signed into law the Agricultural Act of 2014 (P.L. 113-79). As provided in Section 10013 of Title X - Horticulture, on the ESA Implementation in

Pesticide Evaluation Programs, Congress required this final report to be delivered one year after the bill was signed into law. The intent expressed in this provision is to keep the Agencies moving forward as they develop processes that will make it possible to complete Biological Evaluations and Biological Opinions for pesticide consultations, and minimize delays of pesticide registration and registration review decisions.

In addition, the provision is intended to encourage meaningful public participation, and reemphasize that all ESA-mandated RPAs are technologically and economically feasible, that ESA-mandated RPMs are necessary and appropriate, and that the Agencies have ensured public participation and transparency in the development of Biological Evaluations and Biological Opinions, RPAs, and RPMs where appropriate. The conference report for the Agricultural Act of 2014 to accompany H.R. 2642 (https://www.congress.gov/113/crpt/hrpt333/CRPT-113hrpt333.pdf - page 532) includes the following requests that we respond to below:

1. Implementing NAS Report Recommendations

> **Request**: Describe the actions taken and approaches underway to implement the NAS Report's recommendations and otherwise minimize delays in integrating FIFRA's pesticide registration and registration review requirements and the ESA's species and habitat protection processes.

List of Interagency Workshops

In an effort to begin implementing the recommendations on upcoming consultations, the Agencies have held five internal workshops to develop the NAS NRC report interim approaches to address the NAS NRC report recommendations. Significant progress occurred at each of these workshops to improve coordination between the Agencies and develop the technical analyses included in the Biological Evaluations. Each workshop is briefly discussed below, with examples provided of some of the agreements that have been reached thus far.

August, 2013 Inter-Agency Workshop - The Agencies conducted their first technical workshop during the week of August 5, 2013, in which Agency scientists jointly developed the NAS NRC report interim approaches for estimating risks to ESA-listed species from pesticides. The white paper describing the NAS NRC report interim approaches entitled, "*Interagency Approach for Implementation of the National Academy of Sciences Report*" (November 13, 2013) is available at the following link: (http://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf).

As part of the NAS NRC report interim approaches, the Agencies agreed on a three-step consultation process and developed thresholds to evaluate direct and indirect effects to ESA-

listed species and designated critical habitats for Steps 1 and 2 of the three-step consultation process. The Agencies also began to identify the need to develop approaches/methods for addressing the following items:

- A common approach to weight-of-evidence analyses, using quantitative and qualitative information for making NLAA/LAA determinations in Step 2 (and jeopardy and adverse modification critical habitat decisions in Step 3).
- A mechanism for obtaining and sharing the best available geospatial information on species' ranges and critical habitat.
- Definitions for different types of aquatic "bins" (i.e., type of water body) for aquatic species for use in Steps 2 and 3 of the three-step consultation process for exposure modeling. The water body may vary by depth, width, and flow; it may be static, flowing, estuarine, intertidal, subtidal, or offshore marine.
- Guidance on the construction and use of species sensitivity distributions.
- An agreed-upon dataset and method to define agricultural pesticide use areas by aggregation of crop categories in the National Agricultural Statistics Service, Cropland Data Layer.

May 2014 Inter-Agency Workshop - The Agencies conducted their second technical workshop during the week of May 5, 2014, to continue developing and refining the NAS NRC report interim approaches for assessing risks to ESA-listed species from pesticides. In addition, the Agencies developed a draft annotated outline for the Biological Evaluation, which includes Steps 1 and 2 of the three-step consultation process. This draft outline formed the basis of the first three nationwide Biological Evaluations to be completed for the three pilot chemicals (chlorpyrifos, malathion, and diazinon).

November 2014 Inter-Agency Workshop - The Agencies conducted their third internal workshop during the week of November 17, 2014, with the overall goal of fostering an understanding of how to make and support effect determinations for ESA-listed species and designated critical habitat in the draft Biological Evaluations for the three pilot chemicals. These efforts involved highly detailed technical discussions regarding exposure modeling to derive estimated pesticide concentrations in different aquatic waterbodies or "bins" and a preliminary weight-of-evidence approach.

- The weight-of-evidence approach constructs lines-of-evidence from effects data and applies scientific validity and relevance criteria in weighing and aggregating lines of evidence to connect exposures to effects. The Step 2 analysis ultimately informs the Step 3 of the three-step consultation process where overall effects to populations and species

are determined. Progress towards implementing the NAS NRC report recommendations included a series of agreements on the best available science to be applied to the first three pilot chemicals (chlorpyrifos, malathion, and diazinon), with the recognition that the Biological Evaluations will be published in draft form for public comment and with the intention to learn from these pilot cases and modify as needed in the future. Additional progress in implementing the NRC NAS report recommendations made at this workshop include, but are not limited to:

- Approaches to identify data sources and strategies for mapping non-agricultural pesticide uses, methods to consider offsite transport of pesticides via downstream effects and spray drift into the action area, and efforts to obtain refined ESA-listed species location data.
- Potential methods for identifying and reviewing additional open literature data including a discussion of data relevance and data quality.
- Potential methods to qualitatively evaluate the pesticide mixtures.
- A decision framework to ensure the best available data are used to assemble lines of evidence in the weight-of-evidence approach including a strategy to consider the likelihood of potential effects where quantitative data are available, and criteria to determine the level of confidence (weight) to give to each line of evidence a ranking as low, moderate or high.
- Agreement on information required in the Biological Evaluations to support development of the Biological Opinions.

January 2016 Inter-Agency Workshop - The Agencies conducted their fourth internal workshop during the week of January 25, 2016, with the overall goal of fostering an understanding of how to make and support effect determinations for ESA-listed species and designated critical habitat in the draft Biological Opinions for the three pilot chemicals (chlorpyrifos, malathion, and diazinon). The Agencies discussed a number of items that can influence Step 3 of the three-step consultation process:

- What is the Action Area – in relation to a species range, and considering drift and run-off, how much of the action area over-laps with a species range. Within the species range, what the life history stages are associated with this overlap? Is there a seasonality component to these life-history stages?
- Pesticide usage and ESA-listed species/designated critical habitat - What can the Agencies say about the timing of pesticide uses (if specified on the labels) relative to the presence of ESA-listed species/designated critical habitat?

- Species Life Stage - Considering each of the lines of evidence that were analyzed in the Biological Evaluations, what are the anticipated magnitudes of effects and anticipated responses for each species and or their life stages present in the aquatic bins? What additional life stage information needs to be considered? (e.g., years to reach reproductive age, fecundity)? What are the behavioral (social) aspects of the species (e.g., solitary, schooling)? What do we know about the overall number of individuals in the population - in total, and by life stage?
- Habitat - Can the species broaden its range, or are there baseline habitat issues that may be limiting their ability to viably do so? What are these issues and how may the action affect these?
- Other information - What are the other aspects of the species status that may be informative (e.g., population declining, stable, or increasing)?

September 2016 Inter-Agency Workshop

As a result of the workshop and other recent discussions, the Agencies have better defined a path forward for completing the pilot consultations over the next year as summarized below.

- Population level effects analysis tool - The Agencies are working together to create a new tool to more quickly analyze effects of pesticides on ESA-listed species based on predicted estimated exposure concentration. This tool is intended to streamline portions of the Step 3 effects analyses at the population level, provide probabilistic output (e.g., % chance of mortality in % of population), and create greater transparency in the consultation process. This tool provides one method to describe potential effects to species in the Biological Opinions.
- Population models - The Agencies are evaluating the use of simple models for plants and animals that lack complex species-specific models. The Agencies established a sub-team to evaluate the usefulness of simple models for the analyses and the time and resources needed populate and run the models. Given the timeline, it is unlikely that population models will play a large role in the Biological Opinion for the first three pilot chemicals (chlorpyrifos, malathion, and diazinon).
- Pesticide usage data - The types of available pesticide usage data were presented and discussed at the interagency workshop. The Agencies have agreed to work together to determine the most appropriate use of these data in the Step 3 analyses. Pesticide usage data could potentially be incorporated into Step 3 as part of the environmental baseline, as a basis for mitigation discussions with registrants, and/or as a bounding estimate to further characterize exposure (and risk) which is currently based on the highest application rates for use patterns specified in product labels.
- Species range refinements - The Agencies will work together to further refine species ranges based on habitat categories using available data from the U.S. Geological Survey's Gap Analysis Program and EPA's Endangered Species knowledgebase.

- A subgroup Agency staff will meet to reach a common understanding and agreement of the integration and synthesis process that supports the jeopardy and adverse modification conclusion.

Path Forward from the NAS Report's Recommendations

Since receiving the NAS NRC report, the Agencies have been working on the report's overarching recommendation to implement a three-step risk assessment and consultation approach. More detail on the three-step risk assessment and consultation approach is described in Appendix 1. The Agencies are now working to develop Step 3 interim measures that will be used to develop the draft Biological Opinions for the three pilot chemicals (chlorpyrifos, malathion, and diazinon). Additionally, the Agencies are taking recommendations from the June 29-30, 2016, ESA stakeholder's workshop to identify short-, mid-, and long-term recommendations intended to create efficiencies for integration into the ESA section 7 consultation process.

Management and staff from the Agencies continue to work together to complete the consultations for the first five chemicals (chlorpyrifos, malathion, diazinon, carbaryl, methomyl). However, it is important to recognize that the Agencies' work to develop common analytical requirements for Biological Evaluations and Biological Opinions and the desire and requirements around stakeholder involvement has strained existing resources. The Agencies have a finite number of staff to conduct this work and at the same time meet litigation mandated deadlines for the Biological Opinions. Examples of processes the Agencies are simultaneously working on include:

- Detailed data review for the development of Biological Evaluations and Biological Opinions;
- The need to develop scientifically valid analysis methods (Step 3) for the Biological Opinions while still refining the screening and analysis methods for Steps 1 and 2 of the three-step consultation process;
- The requirement to create interactive venues for stakeholder involvement and allow for stakeholder comment on work products; and
- The requirement to provide detailed responses to stakeholder comment on work products.

Looking for Efficiencies in the Consultation Process

The Agencies conducted a joint retrospective review of our work by soliciting ideas from senior managers and scientists working on the three pilot chemical consultations to answer the question, "What efficiencies or improvements can we incorporate into the no effect/may affect determinations made in Steps 1 and 2 of the three-step consultation process moving forward

based on lessons learned from the interagency work thus far?" The Agencies established a workgroup to refine these recommendations and incorporate responses to the efficiencies recommendations provided by CropLife America and the Minor Crop Farmer Alliance to the Agencies on January 21, 2016. This, along with the recommendations provided during the June 29-30, 2016, ESA stakeholder's workshop will help EPA to meet its FIFRA and ESA obligations in coordination with USFWS and NMFS.

In an effort to find efficiencies and thereby minimize delays, EPA compiled information on existing Biological Opinions for the use of pesticides by Federal land managers (e.g., U.S. Forest Service and the Bureau of Land Management). This information will be considered, as appropriate, to understand where the Agencies can potentially leverage existing consultation information for ongoing and future pesticide consultations.

In order to further improve the efficiency of the consultation process, EPA is identifying places where it is practical to make No Effect determinations, or where informal consultation can lead to Not Likely to Adversely Affect determinations.

On-Going Mitigation Efforts during Registration Review

EPA has continued to implement its registration review program, including making preliminary ESA determinations in interim decisions by taxon when feasible. Once the interim scientific methods have been sufficiently vetted in the context of the ongoing pilot consultations, final ESA determinations will be integrated into final registration review decisions. This approach is intended to achieve efficiencies by refining and limiting the scope of consultation as a result of preliminary risk assessments and mitigation measures proposed as part of interim decisions.

In addition to the successful pesticide consultations described below, EPA is working to implement mitigation measures intended to protect ESA-listed species and designated critical habitat as part of stakeholder engagement prior to consultation during its registration review program. These positive outcomes described below underscore the importance of early engagement with stakeholders.

Starlicide - Starlicide™ is an avicide used mainly in feedlots, as well as staging areas in rice growing areas. Typically, Starlicide is used in the form of treated baits and is currently undergoing registration review. Although consultation has not been initiated, it provides an example of positive outcomes from early stakeholder engagement prior to consultation. In the interest of reducing non-target exposure, EPA met regularly with APHIS and the U.S. Rice Federation to discuss ways to minimize exposure and reduce costly data requirements. The U.S. Rice Federation suggested tilling the soil after the application/bait period to bury leftover bait,

making it less accessible to non-target species. This would be a practical mitigation measure that is technologically and economically feasible for the rice use, and may work for some of the other broadcast uses as well. The goal of these outreach efforts is to eliminate or limit the potential for non-target exposures from the rice use and other broadcast uses, subsequently negating the need for the majority of the FIFRA data requirements for Starlicide™. This modification will be reflected in the consultation EPA initiates with USFWS as it works to complete registration review. The Agencies are working towards this kind of successful outcome through collaborative dialogue with stakeholders resulting in technologically and economically feasible mitigation measures, which when implemented have the dual benefits of precluding the need for expensive data requirements, and reducing, or eliminating concerns for ESA-listed species.

Gas cartridges - Gas cartridge products are used to control burrowing mammals. These products are currently undergoing registration review, and informal consultation with USFWS has been initiated. As part of the gas cartridges registration review, EPA and the registrants for the gas cartridge products worked closely together to develop risk mitigation measures and as a result, the gas cartridge registrants have agreed to place risk mitigation measures on their product labels, thus narrowing the scope of consultation. Based on EPA's September 2015 interim decisions on the gas cartridges, Bulletins have been developed to restrict gas cartridge product use in the range of four ESA-listed species including the gopher tortoise, Hualapai Mexican vole, Mount Graham red squirrel, and the Utah prairie dog. The registration review interim decisions on gas cartridges provide an example of achieving risk mitigation for some ESA-listed species prior to consultation.

2. Meeting FIFRA Schedules and Resolving Delays

> **Request**: Include an explanation of how any remaining delays in this integration are expected to be overcome, and a schedule for doing so

Approach to Addressing Litigation on the Agencies Joint-Pesticides Work

EPA is continuing to complete FIFRA assessments for chemicals going through EPA's registration review program and reaching interim decisions for these chemicals which include mitigation that is intended to be protective of ESA-listed and non-listed species and designated critical habitat with the intent that we will finalize the decisions once the ESA methods have been vetted and implemented in a phased and iterative approach.

In the interest of minimizing litigation and meeting the requirements of timely EPA registration and registration review actions in Section 3 and 33 of FIFRA, the Agencies agreed to coordinate completion of nationwide consultations. EPA implemented a three-pronged strategy that is

intended to address effects to ESA-listed species and designated critical habitat by focusing resources on areas where we can achieve the most protections.

First, EPA is engaging with NMFS and USFWS on ESA consultation work through registration review. For example, the first five chemicals (chlorpyrifos, malathion, diazinon, carbaryl, and methomyl) selected for ESA consultation focus on chemicals with higher risk, resulting in the greatest potential benefits for ESA-listed species while addressing litigant concerns. Consistent with the interagency "shared scientific approaches" and "day forward approach," once fully developed and vetted, our shared scientific approaches will be applied to pesticide reviews from that point in time and going forward rather than reworking assessments and decisions already completed.

Second, for all new herbicide-tolerant crop uses, EPA is using methods consistent with the *Overview Document* (January, 2004) for endangered species assessments. The *Overview Document* details EPA's general risk assessment approach for pesticides and its specific application to endangered species concerns. The *Overview Document* can be found at the following link: https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf. This approach is intended to timely address EPA's FIFRA and ESA obligations in ways that will make the best use of the Agencies staff and resources while EPA is working to develop and implement methodologies to address the NAS NRC recommendations. For example, through implementation of the *Overview Document*, EPA is continuing to work with USFWS regional-based field offices to make effects determinations on the chemicals dicamba and 2-4 D where soybeans, cotton, and corn are grown.

Third, for new active ingredients, EPA will compare their potential hazards to the registered alternatives to the proposed registration. This will allow stakeholders to compare the relative risks of the proposed registration to available alternatives. EPA believes that older, currently registered chemicals typically have the potential to pose greater risks to ESA-listed species than do the newer, generally lower-risk pesticides being introduced into the marketplace today, and that the comparative hazard information will illustrate this to all stakeholders. This additional hazard information contributes to information sharing, promotes communication with the public, and improves relationships and trust with stakeholders.

Resource Constraints and Challenges

The interim scientific methods developed in response to the NAS NRC report recommendations are comprehensive approaches intended to evaluate nationwide uses of pesticides on ESA-listed species and designated critical habitat and are designed to blend the ESA consultation process and the FIFRA pesticide registration processes to the extent practicable. While the Agencies

have worked collaboratively to develop common interim methods for Steps 1 and 2, it is important to note that there some topics for which the Agencies have not yet reached resolution and have agreed to continue further discussion as part of the interim method development work for Step 3. It is also important to recognize that the interim scientific methods used to develop the Biological Evaluations including the involvement and integration of stakeholder concerns have strained existing resources of the Agencies. The Agencies have a finite number of staff to conduct this work and at the same time meet litigation mandated deadlines based on existing ESA-related settlement agreements. Additionally, EPA has been sued for failure to meet its ESA obligations on new chemical registrations, potentially resulting in further resource constraints. The Agencies are actively working to refine and streamline the current methods based on stakeholder engagement to create a process that will support successful pesticide consultations for future actions and will continue to look for efficiencies in the FIFRA registration review process and the ESA consultation process to address these resource constraints as we continue to implement this work.

An example of added complexity and increased review time for a registration's risk assessment is for herbicide uses, such as 2,4-D Enlist and dicamba on herbicide tolerant crops. As mentioned above, EPA intends to complete endangered species assessments for new herbicide tolerant crop uses based on the Overview Document- method. The EPA is completing these effect determinations as resources allow and will consider a subset of new chemical registrations for future pesticide consultations as part of the future schedule development. To maximize impact within these limited resources, the initial registrations for herbicide tolerant crops are not nationwide in scope, and to the extent practical have been limited in scope to situations where EPA can make "no effect" decisions. EPA has already piloted this approach with the registration of Enlist Duo.

Programmatic Consultations to Streamline Future Pesticide Consultations

Currently, the Agencies are fully absorbed with meeting the litigation deadlines associated with completing ESA section 7 consultations. However, as we continue to plan our out-year work on ESA compliance, we will explore the development of programmatic consultations to meet ESA consultation requirements.

3. Ensuring Public Participation and Transparency

> **Request:** Describe approaches and actions to ensure public participation and transparency, the Managers specifically expect the report to address experience with the process described in EPA's March 2013 paper, "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and

Prudent Alternatives" and any modifications of that process that have been adopted or are anticipated.

Ensuring Public Participation and Transparency

The Agencies' efforts to improve transparency for pesticide consultations began as early as May, 2011, with the Minor Crop Farmer Alliance workshop, held in Denver, Colorado, which addressed grower and user concerns. There was general agreement that information was needed to clarify and confirm product labeling information, identify where crops are grown, and that growers need to be engaged early and often. The meeting minutes and materials provided for and discussed at the workshop can be found at the following link: http://www. ffva.com/imispublic /Content/NavigationMenu2/AgResources/Aglinks/Meetingmaterials/default.htm. Copies of the individual presentations can be found on the following links: Florida Fruit & Vegetable Association (www.ffva.com) and the California Citrus Quality Council (http://calcitrusquality.org/).

In response to the stakeholder feedback gained in 2011, the Agencies prepared and provided for public comment the paper entitled, "*Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives*" (hereafter referred to as the Stakeholder Paper). The Agencies finalized the Stakeholder Paper in March, 2013. The paper can be found the following link: www.regulations.gov, in the following docket: EPA-HQ-OPP-2012-0442.

Public Participation Process

EPA has existing processes for registration, registration review, and consultation which provide multiple opportunities for stakeholder engagement and public comment. Although Federal law only requires limited public participation in the pesticide registration process, EPA's Pesticide Program began implementing a public participation process for certain registration actions in October 2009. The public participation process for registration actions provides a meaningful opportunity for the public to comment on major registration decisions at a point in the registration process when comprehensive information and analysis are available. EPA currently uses the outlined public participation process for the following types of applications:

- New active ingredients
- First food use
- First outdoor use
- First residential use

- Other actions of significant interest

The current post-registration review process – known as registration review – was created by section 3(g) of FIFRA and mandates that EPA review pesticides not less often than every 15 years. Currently there are over 700 registration review "cases" that include over 1,100 pesticide active ingredients. Under section 3(g)(l)(A)(ii), EPA has established procedures for registration review in its final rule published in the Federal Register (71 FR 45,732, August 9, 2006, as amended at 73 FR 75595, December 12, 2008) and codified at 40 CFR Part 155 Subpart C - Registration Review Procedures. Under the procedures established per 40 CFR part 155 Subpart C, three specific time points have been identified for public notification and comment during registration review:

- Initiation of a pesticide's reevaluation
- When a draft risk assessment has been conducted
- A proposed registration review decision

In addition to the public review and comment periods outlined above, EPA may meet with stakeholders at any time during registration review, either by EPA or the stakeholder's request (40 CFR Part 155.52).

Early Stakeholder Engagement

As a result of EPA's Stakeholder Paper, EPA has held focus meetings the start of registration review for pesticide active ingredients. This change brings the affected stakeholders into EPA's review process at the earliest point of a pesticide's registration review cycle. Many of the focus meetings have resulted in registrants agreeing to improve the pesticide label in order to clarify the use pattern and best estimate environmental exposure.

Additionally, the 2013 paper outlined the transparent stakeholder process for the Agencies to receive comments on a draft Biological Opinion written by USFWS and NMFS. According to the intended process, once written, the USFWS and NMFS will provide EPA with the draft Biological Opinion for the purpose of analyzing the reasonable and prudent alternatives. EPA will make this draft Biological Opinion available for public comment. All comments will be submitted to EPA, although the applicant may send a copy of its comments directly to USFWS and NMFS. EPA will organize all of the public comments to aid the USFWS and NMFS in their review of the comments and will highlight comments of particular note. EPA will provide the USFWS and NMFS with all of the comments that are submitted in response to the draft Biological Opinion. The Agencies will pilot this process in 2017.

List of Stakeholder Workshops

Since the release of the NAS NRC report in 2013, the Agencies have held a number of workshops for external stakeholders. A brief chronological summary of these stakeholder workshops and associated accomplishments are provided below:

November 2013 Stakeholder Workshop - The NAS NRC report interim approaches developed at the Agencies' technical workshop in August, 2013 were presented to the public during a stakeholder workshop on November 15, 2013. Presentation materials from the stakeholder workshop are available at the following link: http://www2.epa.gov/sites/production/files/2015-09/documents/nas-rollout.pdf. At this workshop, the Agencies communicated that the NAS NRC report interim approaches will be incorporated into the risk assessment process on a "day forward approach."

April 2014 Stakeholder Workshop - On April 22, 2014, at the request of stakeholders, the Agencies held a public workshop to provide a forum for stakeholders to present scientific and technical feedback on the NAS NRC report interim approaches. Representatives from the pesticide industry and non-governmental organizations attended the workshop and provided feedback. Members of the original NAS NRC panel, Defenders of Wildlife, and industry stakeholders presented approaches and methods for refining Steps 1 and 2 of the three-step consultation process (see Appendix 1), evaluating geospatial information on species and crop location, using species biological information and critical habitat attributes, and integrating weight-of-evidence and uncertainty analysis as part of the risk assessment process. The scientific and technical presentations are available in the public docket (EPA-HQ-OPP-2014-0233) which can be found at the following link: http://www.regulations.gov/.

October 2014 Stakeholder Workshop - The third stakeholder workshop, held on October 6, 2014, included presentations from the USFWS on the effort to obtain ESA-listed species range maps and from EPA on the status of the Agencies' work on the three pilot chemicals (malathion, chlorpyrifos, and diazinon) to further develop and implement the NAS NRC report interim approaches. There was significant stakeholder interest in potential changes to current methods for modeling aquatic exposure, refinements to reduce the number of species for which consultation is required, and the timeline for completion of the draft Biological Evaluations and associated decisions relative to modeling, use of probabilistic methods, and the weight-of-evidence analysis. External stakeholders, mainly pesticide industry representatives, presented on the role of multiple species and crop attributes in understanding the potential for exposure, characterization of uncertainty in aquatic risk assessments, probabilistic methods, and weight-of-evidence analysis.

April 2015 Stakeholder Workshop - A fourth stakeholder meeting held on April 15, 2015, reviewed the Problem Formulation Framework, including the description of the Federal action, mapping pesticide use patterns, species ranges, and the risk hypothesis and weight-of-evidence approach . More information about this meeting, including the Agencies' presentations can be found at the following link: http://www.epa.gov/endangered-species/assessing-risks-endangered-and-threatened-species-pesticides-4th-interagency.

June 2016 Stakeholder Workshop – Prior to the June 2016 workshop, two conference calls were held with stakeholders who participated in previous workshops to identify agenda topics and solicit ideas for a meeting format that would allow for increased participation and interaction between stakeholders and agency staff. Based on feedback from these conference calls, the Agencies, in conjunction with a steering committee composed of representatives from the Agencies, industry, and non-governmental organizations, held a two-day stakeholder workshop on June 29 - 30, 2016. The workshop was attended by representatives of affected industry and grower groups, consultants, conservation and other non-governmental organizations, the Agencies and USDA. The workshop addressed issues of concern to the Agencies and stakeholders, including aquatic exposure modeling, defining proper use of water monitoring data in the ESA context, geographic and non-geographic refinements to risk assessment methods, and improvements to the weight-of-evidence approaches for determining risks to ESA-listed species. The Agencies are considering recommendations from the June 29-30, 2016, ESA stakeholder's workshop to identify short-, mid-, and long-term activities for refining the interim methods used to develop the draft Biological Evaluations for the three pilot chemicals. The Agencies expect to implement a number of these recommendations in the final Biological Evaluations for the three pilot chemicals and upcoming draft Biological Evaluations for carbaryl, methomyl, atrazine, glyphosate, simazine, and propazine, based on a phased and iterative approach as resources and litigation mandated deadlines specified in existing ESA-related settlement agreements allow.

4. Establishing Timelines for Specific Actions

> **Request:** In identifying specific actions yet to be undertaken, the report should provide a schedule for the initiation and completion of each, which should be realistic and allow for public participation.
>
> *Focusing on Establishing Clear and Transparent Timelines*

The Agencies are working together on the following actions to identify and implement efficiencies in the ESA consultation process. To allow additional time for the public to review the first round of draft Biological Evaluations for the three pilot chemicals (malathion,

chlorpyrifos, and diazinon), EPA released a large portion of these Biological Evaluations in December 2015.

The completed draft Biological Evaluations were released for a 60-day public comment in April 2016. The goal of the public comment period and the stakeholder workshop was to solicit recommendations to refine the interim approaches. This information can be found at: (http://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and). During the 60-day comment period on the draft biological evaluations, EPA received over 78,600 comments, with about 120 substantive comments meriting detailed review. The EPA is currently reviewing these comments as well as recommendations from the June 2016 stakeholder workshop for potential integration into the final nationwide Biological Evaluations for the three pilot chemicals in January 2017.

The Agencies have specific litigation driven deadlines between now and 2022 to complete consultation on nine chemicals (Group 1 – three pilot chemicals - chlorpyrifos, malathion, and diazinon; Group 2 – carbaryl and methomyl; Group 3 - glyphosate, atrazine, simazine, and propazine). The NMFS and FWS *draft* Biological Opinions for Group 1 (chlorpyrifos, malathion, and diazinon) are proposed to be released for public comment by May, 2017. The *final* nationwide Biological Opinions for the first three pilot chemicals (chlorpyrifos, malathion, and diazinon) are scheduled for release in December, 2017. Concurrent with the work on these three pilot chemicals in 2016 and 2017, the Agencies began development of the draft Biological Evaluations for the Group 2 chemicals, carbaryl and methomyl, with an anticipated release date by the spring of 2017. Group 3 chemicals (glyphosate, atrazine, simazine, and propazine) have Biological Evaluations due June 2020 and Biological Opinions due December 2022. The Agencies are also working on a pesticide workplan beyond 2022 to ensure that consultations are completed in a timely and efficient manner.

5. Using Best Available Science

> **Request:** The report should comprehensively explain why the approaches and actions that have been or will be taken to address Congress's concerns in enacting this provision utilize the best available science, assure that reasonable and prudent alternatives presented in biological opinions are technologically and economically feasible and that reasonable and prudent measures are necessary and appropriate.

The Agencies held a 3-day workshop in September 2016 and are currently meeting weekly to develop the analytical methodology for Step 3 of the three-step consultation process and utilize stakeholder recommendations as we move from the development of Biological Evaluations to Biological Opinions. This includes developing specific processes to ensure the best available science is being used in the development of analysis techniques to understand the effects of EPA's proposed action. For example, the Agencies are working together to create a new tool to

more quickly analyze effects of pesticides on ESA-listed species based on predicted estimated concentrations. This tool is intended to streamline portions of the Step 3 effects analyses at the population level, provide probabilistic output (e.g., % chance of mortality in % of population), and create greater transparency in the consultation process. The Agencies expect to hold a sixth interagency workshop in late 2016 to further discuss the integration and synthesis of data considered as part of the Step 3 Framework.

The interim technical methods the Agencies are developing have also been published or presented at a number of scientific and stakeholder forums to receive feedback and provide updates on scientific methods to assess pesticide risks to ESA-listed species. As a result, the Agencies are furthering the development of the best available science being used in the development of the Biological Evaluations and Biological Opinions for this effort. Appendix 2 lists presentations given to support Agency technical work on pesticides. Agency staffs have also published a number of peer reviewed research publications related to this work:

- Macneale, K.H., Spromberg, J.A., Baldwin, D.H., and Scholz, N.L. 2014. A modeled comparison of direct and food web-mediated impacts of common pesticides on Pacific salmon. Public Library of Science ONE, 9:e92436.
- Laetz, C.A., Baldwin, D.H., Hebert, V., Stark, J.D., and Scholz, N.L. 2014. Elevated temperatures increase the toxicity of pesticide mixtures to juvenile coho salmon Aquatic Toxicology, 146:38-44.
- Laetz, C.A., Baldwin, D.H., Hebert, V., Stark, J.D., and Scholz, N.L. 2013. The interactive neurobehavioral toxicity of diazinon, malathion, and ethoprop to juvenile coho salmon. Environmental Science & Technology, 47:2925-2931.
- Laetz, C.A., Hecht, S.A., Incardona, J.P., Collier, T.K., and Scholz, N.L. 2015. Ecological risk of mixtures. In: Aquatic ecotoxicology: advancing tools for dealing with emerging risks. C. Amiard-Triquet, J.-C. Amiard, and C. Mouneyrac (eds). Academic Press, pp. 441-462.
- Brander, S., Hecht, S., Kuivila, K. The Challenge: "Bridging the gap" with fish: Advances in assessing exposure and effects across biological scales. 2015. Environmental Toxicology and Chemistry Globe Series.

a. Among other matters, this explanation should explain how the substantive and procedural concerns that resulted in the vacating of certain portions of the regulation appearing in Subpart D of Part 402 of the Code of Federal Regulations in *Washington Toxics Coalition v. USEPA*, 457 F.Supp. 2d 1158 (W.D. Wash. 2006), have been overcome;

In lieu of the vacated 2004 counterpart regulations, the Agencies are developing an ESA consultation process by establishing joint, agreed-upon interim scientific methods for Steps 1, 2, and 3 as envisioned in the 2013 NAS-NRC report. This approach ensures the development of three pilot Biological Evaluations and Biological Opinions that make use of the best available data and are consistent in the technical methodology and approaches to address effects to ESA-listed species and designated critical habitat.

b. how the January 4, 2004 letter from the Director of the U.S. Fish and Wildlife Service and Assistant Administrator of the National Marine Fisheries Service to the Principal Deputy Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances of the Environmental Protection Agency has been updated and revised; and how the Alternative Consultation Agreement entered into in August, 2004 by the Acting Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances of the Environmental Protection Agency, the Director of the U.S. Fish and Wildlife Service, and the Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration has been revised or whether it is scheduled to be revised.

There is no current schedule to revise the aforementioned 2004 letter or the Alternative Consultation Agreement. The Agencies are moving forward pursuant to the NAS NRC report and the interim methods as described throughout this report. As part of completing consultation on the first five pesticides, the Agencies will document the jointly developed and agreed upon methods in a Memorandum of Understanding or some other appropriate documentation. We are also discussing and assessing a process for a programmatic approach to the pesticide consultations in order to streamline and increase ESA implementation efficiency into the future.

6. Accomplishing ESA Implementation

Request: The report should include an update of the study and report on how ESA implementation is being undertaken while minimizing the impacts on persons engaged in the production of agricultural food and fiber commodities and other affected pesticide users and applicators.

Major Accomplishments Achieved to Further the ESA Consultation Process

In addition to the accomplishments discussed above, the Agencies have made significant strides to further the development of a robust set of ESA consultation documents (*i.e.* releasing draft Biological Evaluations that used interim scientific methods) that include joint Agency collaboration and stakeholder involvement. The draft Biological Evaluations are currently being refined based on comments received and the June 2016 stakeholder's workshop. Building on the interim methods collaboratively developed for Steps 1 and 2, the Agencies have continued to

refine the technical analyses and processes to produce Biological Evaluations that we can now build on to develop Biological Opinions that are scientifically credible, legally defensible, and take into account the concerns and advice voiced by key stakeholders. As described below, a significant effort has been made to align, where appropriate and applicable, the technical analyses of the Agencies as we develop the Biological Evaluations and Biological Opinions for this work.

Joint Technical Analyses

- Agency agreement on geospatial data to define pesticide use areas for agricultural and non-agricultural use patterns.
- Guidance on the construction and use of species sensitivity distributions to derive acute toxicity thresholds. The SSD toolbox can be found at the following link: https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments
- Discussing methods for qualitative analysis of mixtures, inert ingredients, and surfactants.
- Agency agreement on aquatic habitat bins which include static, flowing, and estuarine/marine habitats and methods for predicting regionally-specific aquatic exposure concentrations for each bin based on existing EPA models, and assignment of all aquatic ESA-listed species including different life stages (e.g., juvenile vs. adult) to the appropriate bins.
- Agency agreement on the review of all registrant-submitted and open literature data for the three pilot chemicals (chlorpyrifos, malathion, and diazinon) including associated thresholds for each line of evidence and taxonomic group and associated data arrays for the three pilot chemicals.
- Agency compilation and agreement on life history data (*e.g.*, diet, body weight, habitat, etc.) for all ESA-listed species including identification of model input parameters based on this information.
- Development of tools to advance and automate the estimation of pesticide exposures and effects for ESA-listed species for EPA's nationwide assessments, resulting in the following:
    - Automation of thousands of aquatic modeling runs and aid in the post-processing of these results. These tools will automatically generate graphs and tables including exposure distribution over time to help characterize the duration and magnitude of exposure;

- Integration of existing terrestrial modeling tools (T-REX, T-HERPS, TerrPlant, AgDRIFT, Bee-REX) to make effects determinations for ESA-listed mammals, birds, reptiles, amphibians, terrestrial plants, and invertebrates in one model (TED – Terrestrial Effects Determination tool);
- Implementation of probabilistic models including TIM and McNEST that assess pesticide risks to birds;
- Tools that better portray all of the toxicity effects data including the data array builder. EPA developed a data array builder that identifies and groups data (e.g., endpoints specific to family, species and endpoints), providing a graphic representation of relevant toxicity data. The data array builder can be found at the following link: http://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments#Effects. ; and
- Development of new tools and aggregated models intended to analyze and visualize the estimated exposures and available effects data in an automated fashion. Provisional models released as part of the December 2015 draft Biological Evaluation sections can be found at the following link: http://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments.

- The Agencies are currently working together to develop interim methods for Step 3 of the three-step consultation process including further tool development for population-level analyses, agreement on the risk hypothesis, lines of evidence, and criteria to evaluate and assign weight or confidence to each line of evidence for use in the development of the Biological Opinions.

Specific Results from Workshops

Through the stakeholder workshops conducted since 2014, the Agencies have provided the public, including producers of food and fiber commodities, the opportunity to review, comment, and provide recommendations on the interim scientific methods being used to develop the Biological Evaluations and Biological Opinions for the first three pilot chemicals (chlorpyrifos, malathion, and diazinon).

As part of the USFWS presentation on the effort to obtain geospatial data for ESA-listed species for use in pesticide Biological Evaluations and Biological Opinions at the October 2014 Stakeholder Workshop, USFWS reported plans to request refined species range data (sub-county where available) from species experts within their Field Offices. USFWS also reported that a collaborative process had been developed with the FIFRA Endangered Species Task Force (FESTF) and that a large component of this effort would consist of FESTF developing species

range map kits in three phases for review and editing by the USFWS species experts. Phase 1 of this effort includes all species, excluding mammals and plants, for the lower 48 contiguous states, Alaska, Puerto Rico and U.S. Virgin Islands. Phase 2 includes mammals and plants for the area covered by Phase 1 and Phase 3 includes range maps for plants and other species occurring in the Pacific Islands.

The USFWS Field Offices were assigned to help review and refine species range maps for each species within their jurisdiction. This was a huge undertaking that required hundreds of hours of work from species experts across the nation. The USFWS has completed this task and range maps for all 1,746 candidate, proposed, and ESA-listed species and listed species experimental populations is now complete. We estimate that approximately 50 percent or more of species range maps are now mapped at a sub-county level that more accurately reflect the current range of the species. An example of a refined species range map (i.e., county to sub-county) for the following fish species, the Ash Meadows speckled dace is provided below (Figure 1). This example demonstrates the dramatic difference between a county-level range map versus a current, more refined range map. The USFWS will continue to refine species range maps where feasible (e.g. use USGS's National Gap Analysis Program species range maps where available) and beneficial for the pesticide consultations. Other examples of these refinements may include the mapping of suitable habitat types for species and/or identifying and mapping topographic features (e.g., mountain ranges, elevation).

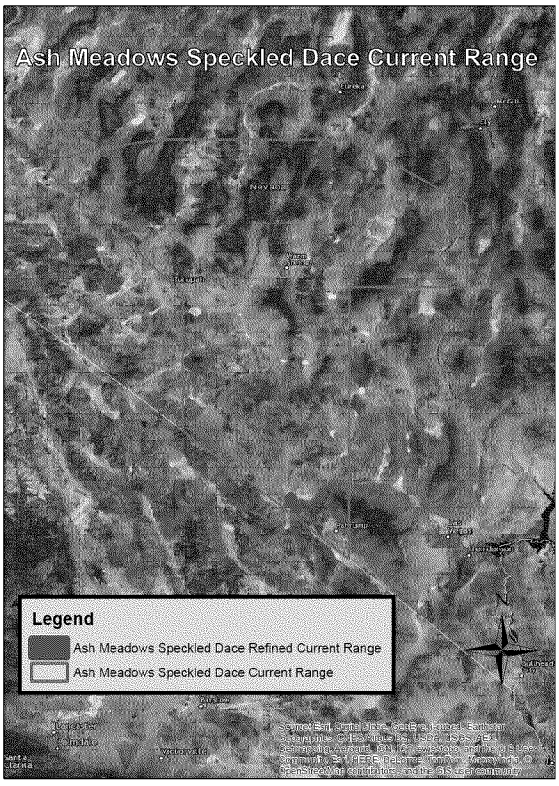


Figure 1. Ash Meadows Speckled Dace Current Range Map.

At the November 2014 interagency workshop, the Agencies reached agreement on the process by which EPA will, in appropriate circumstances, seek to get ESA-listed species mitigations in place early in the registration review process. Mitigation focus is on avoidance and minimization through label changes at Steps 1 and 2 of the three-step consultation process, with these implemented as changes to the proposed action. EPA will work with the registrant to get label clarifications and understand use patterns. Timing of agreement on label changes will depend on interactions with the registrant(s).

The Agencies are also exploring, with the registrants, how to incorporate mitigation measures into the ESA section 7 consultation process. For those registrations when the registrant(s) is/are willing to make voluntary changes to the label, EPA will send a package of information to NMFS and USFWS between the draft and final Biological Evaluations. This will be sent as a change to the Federal action. The package will include a transmittal letter from the Director of EPA's Pesticide Re-evaluation Division summarizing the negotiations with the registrant to obtain label changes, a table capturing the label changes, and the commitment letters from the registrants with the anticipated dates for those changes.

Bulletins Live

EPA's Endangered Species Protection Program (ESPP) is the EPA program for addressing the requirements of the ESA in connection with EPA's implementation of FIFRA. In addition to the stakeholder workshops described below EPA also uses the web application "Bulletins Live Two," to set forth geographically specific pesticide use limitations for the protection of threatened and endangered species and their designated critical habitat. "Bulletins Live Two" can be found at the following link: http://www.epa.gov/endangered-species/endangered-species-protection-bulletins.

"Bulletins Live Two" is geo-coded making it possible for users to zoom in and out and focus on their area of interest, conduct searches for products (by name and EPA registration number) in addition to active ingredients, and download printable Bulletins. These upgrades, implemented in 2015, included:

- An interactive map;
- Different base maps (satellite, street, geographic, etc.) to help users determine if their application area is in a pesticide use limitation area;
- Advanced searches for active ingredient, product (by name or registration number), and/or location (state, county, specific address); and
- An enhanced system to receive public comments on draft Bulletins.

These upgrades allow the web application setting forth species protections to be more easily accessible and understandable for users likely to be affected by species protections.

Completed Consultations

The Agencies have also successfully completed pesticide consultations for several pesticide actions, which are discussed in further detail below. Through early engagement between the Agencies and affected stakeholders, the Agencies developed mitigation measures that consider existing best management practices (e.g., California Pesticide Regulation's Endangered Species Custom Realtime Internet Bulletin Engine PRESCRIBE system) and increased dialog between those stakeholders during the consultation process.

- Silica - Silica (Diatomaceous Earth) is an insecticide that has undergone registration review. EPA and USFWS successfully completed informal consultation on 57 ESA-listed species that may be directly or indirectly affected by the use of silica. USFWS concurred with EPA's determination that silica may affect, but is not likely to adversely affect or has no effect on these species.

- Rozol - Rozol™ is an anticoagulant rodenticide used to control black-tailed prairie dogs. The consultation was the result of a lawsuit in which the court-ordered EPA to cancel the Rozol's™ registration. EPA and USFWS worked collaboratively with stakeholders (registrants) early during the consultation to identify conservation measures that protect species and their critical habitat. Early mitigation termed "conservation measures" was agreed to prior to the final Biological Opinion. Incorporation of conservation measures protecting species and their designated critical habitat resulted in a no jeopardy conclusion, making RPAs unnecessary. Technologically and economically feasible RPMs were developed collaboratively among USFWS, EPA, and the registrant. The consultation was completed efficiently and species protections put in place quickly.
- Kaput - Kaput™ is another anticoagulant rodenticide used to control black-tailed prairie dogs. It is similar to Rozol™, but contains a different active ingredient. Kaput™ was not yet registered. The Agencies built upon their success from the Rozol™ consultation and applied the same early stakeholder engagement strategy to implement risk mitigation measures that would support a no jeopardy conclusion, thus negating the need for RPAs, and achieving species protections through negotiated RPMs. A Biological Opinion was completed for Kaput™ prior to registration of the product. The measures outlined in the Biological Opinion were then made conditions of registration for the product. As a result, the product, Kaput™, came on the market with these species protections already in place.
- Biological Opinion for thiobencarb implemented - Recent successes illustrate necessary and appropriate RPMs can be achieved through early collaboration and stakeholder engagement. Thiobencarb is one of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. Early engagement between NMFS, EPA, the California Department of Pesticide Regulation, the registrant, and the California Rice Commission allowed EPA and NMFS to develop bulletins that required applicators to follow the California Department of Pesticide Regulation's preexisting permitting requirements for thiobencarb use on rice in California. NMFS considered and used existing state programs to mitigate risks to species and protect designated critical habitat. This resulted in a no jeopardy conclusion.
- Biological Opinion for diflubenzuron, propargite, and fenbutatin-oxide completed - Diflubenzuron, propargite, and fenbutatin-oxide are three of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. NMFS completed the Biological Opinion on December 24, 2014. EPA and NMFS worked with the registrants to identify pesticide uses that posed the greatest risks to salmonids. In working with NMFS, the registrants proposed several label modifications to reduce risk to the species that were incorporated into the Biological Opinion's effects analysis. Unfortunately even with those label changes, pesticides concentrations were still

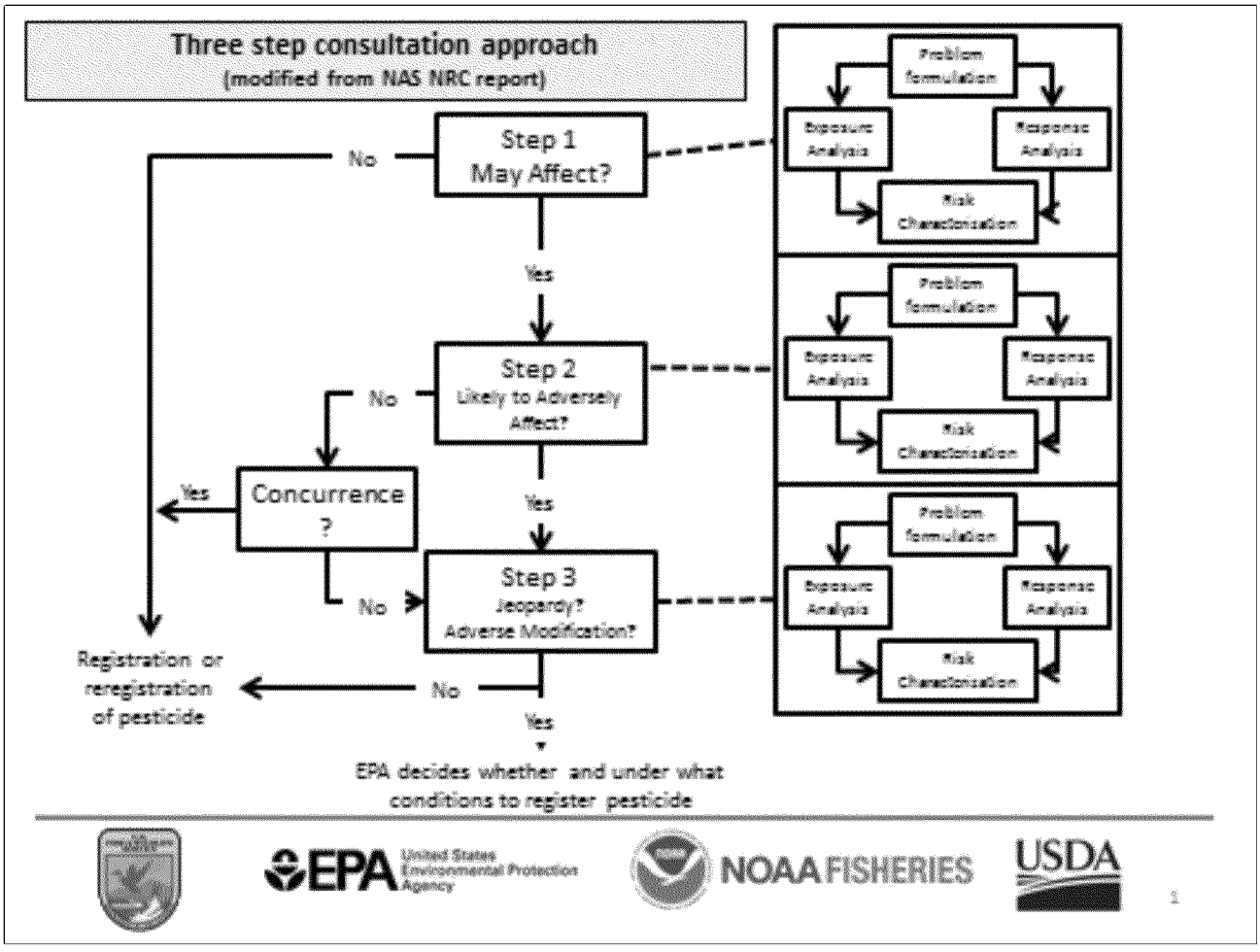
determined to be at levels sufficient for reductions in ESA-listed species population and abundance that resulted in a jeopardy conclusion. EPA is currently working on developing alternative RPAs to present back to NMFS to implement the Biological Opinion.

Conclusion:

The Agencies are committed to producing Biological Evaluations and Biological Opinions that are scientifically credible, legally defensible, and produce tangible benefits to species conservation. The Agencies are equally committed to continue a robust dialogue with all of our stakeholders to ensure transparency throughout the pesticide consultation process that fully considers effects to and from agriculture. The workshops and meetings held between the Agencies and with the stakeholders have created a continued spirit of cooperation and dialog on this work. Completed tools and methodologies on the part of the Agencies have set the stage for long-term improvements and efficiencies to the ESA consultation process.

Appendix 1: NAS NRC Report Recommendation: The Three-Step Approach

The Agencies are addressing the NAS NRC report overarching recommendation to implement a three-step risk assessment and consultation approach, as displayed in the graphic below.



Step 1 - (No Effect/May Affect determinations) - EPA makes the no effect/may affect determination independently of NMFS and/or USFWS at Step 1. If EPA determines that a pesticide's registration (or as more commonly known, reregistration), will have no effect on particular ESA-listed species, it may move forward with or continue a pesticide's registration without consulting with NMFS and/or USFWS. If EPA determines that a pesticide's registration may affect an ESA-listed species, the pesticide's potential impact on ESA-listed species must be considered under Step 2. The No Effect/May Affect determination will largely be based on the overlap of the action area with the ESA-listed species' ranges and designated critical habitats (*i.e.*, any species or critical habitat that overlaps with the action area will be considered a "may affect"). The action area will be defined by identifying pesticide use areas (*i.e.*, the pesticide use

footprint) based on currently registered labeled uses (*i.e.*, the proposed action). In addition, the action area will include a footprint that extends beyond the use sites to incorporate off-site transport including pesticide spray drift and runoff.

Step 2 - (NLAA/Likely to Adversely Affect (LAA) determinations) - EPA determines whether a pesticide's registration is LAA or NLAA ESA-listed species. When EPA determines that an effect is NLAA, they must seek concurrence from the Services. When EPA determines that an effect is LAA, the Agencies enter into formal consultation, and Step 3 is initiated. To determine whether the call for an ESA-listed species and designated critical habitat is an NLAA or LAA, a weight-of-evidence approach that evaluates risk hypotheses and associated lines of evidence will be used. Exposure values will be based primarily on existing fate and transport model results that assess the range of labeled uses of the pesticide (rates, methods). Supporting documentation for existing models can be found at the following link: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment.

Step 3 (Jeopardy/No Jeopardy and Adverse Modification/No Adverse Modification determinations) - For all of those species and critical habitat designations found to warrant determinations of LAA, NMFS and/or USFWS will determine jeopardy or no jeopardy and adverse modification or no adverse modification for these resources, respectively. These determinations will be based on a weight-of-evidence approach that evaluates risk hypotheses and associated lines of evidence for each of these ESA-listed species.

Appendix 2: Presentations Given to Support Federal Agency Technical Work on Pesticides

Session Title	Speakers	Meeting
Interim Methods Used in the Biological Evaluations to Estimate Risk to Individuals of Threatened and Endangered Species from the Use of Pesticides	Melissa A Panger, USEPA Amy Blankinship, USEPA Tony Hawkes, NOAA Nancy Golden, FWS	SETAC 2016
Assessing Risks to Plants under the Endangered Species Act Process	Sara Pollack, FWS Elizabeth Donovan, USEPA Amy Blankinship, USEPA David Baldwin, NOAA	SETAC 2016
Estimating the proportion of a bird population exposed to a single pesticide	Nancy Golden, FWS Kristina Garber, USEPA Jennifer Connolly, USEPA Sara Pollack, FWS Andrew Raab, FWS Thom Hooper, NOAA	SETAC 2016
Use of population modeling in national Endangered Species Act Consultations with Pesticides	Julann A. Spromberg, contractor with NOAA Scott Hecht, NOAA George Noguchi, FWS Kristina Garber, USEPA	SETAC 2016
From Biological Evaluation to Biological Opinion: What to expect next with the National Pesticide Consultations	Scott A. Hecht, NOAA Karen Myers, FWS Melissa Panger, USEPA	SETAC 2016

Update on Methods Used to Estimate Aquatic Pesticide Exposure to Threatened and Endangered Species	Charles Peck, USEPA Colleen Rossmeisl, USEPA Jim Carleton, USEPA Tony Hawkes, NOAA Ryan DeWitt, NOAA George Noguchi, FWS	SETAC 2016
Characterizing Pesticide Exposure to Threatened and Endangered Species with GIS	Ryan DeWitt, NOAA Thom Hooper, NOAA Keith Paul, FWS George Noguchi, FWS Jennifer Connolly, USEPA Steve Lennartz, USEPA	SETAC 2016
ESA Draft Biological Evaluations and Path Forward	Anita Pease, EPA	CropLife America and Responsible Industry for a Sound Environment Spring Conference, 2016
Modeling pesticide exposures and effects to individuals of a listed species	Kristina Garber, EPA	CropLife America and Responsible Industry for a Sound Environment Spring Conference, 2016
Step 3: An Evolving Approach to Endangered Species Act Pesticide Consultations	Cathy Tortorici, NMFS	CropLife America and Responsible Industry for a Sound Environment Spring Conference, 2016
Weight-of-Evidence: An evolving approach to ESA pesticide consultations	Cathy Tortorici, NMFS	CropLife America and Responsible Industry for a Sound Environment Spring Conference, 2016
Use of toxicological data in the assessment of pesticide risk to threatened and endangered species	George Noguchi, USFWS; Sara Pollack, USFWS; Melissa Panger, EPA; David Baldwin, NMFS; Pat Shaw-Allen, NMFS	Society of Environmental Toxicology and Chemistry (SETAC), 2015

Use of species sensitivities distributions and species grouping strategies in national-level endangered species risk assessments	Amy Blankinship, EPA; Kristina Garber, EPA; Matthew Etterson, EPA; Cathy Laetz, NMFS; Sara Pollack, USFWS; Pat Shaw-Allen, NMFS	SETAC 2015
A Weight-of-Evidence Approach for Making Effects Determinations for Federally Listed Species and Pesticides	Nancy Golden, USFWS; Melissa Panger, EPA; Scott Hecht,NMFS	SETAC 2015
Aquatic Modeling to Estimate Pesticide Exposure to Threatened and Endangered Species	Mark Corbin, EPA; Chuck Peck, EPA; Tony Hawkes, NMFS; George Noguchi, USFWS	SETAC 2015
Inclusion of multiple stressors in determinations of pesticide risk to threatened and endangered species	Cathy Laetz, NMFS; David Baldwin, NMFS; Melissa Panger, EPA; Karen Myers,USFWS	SETAC 2015
Assessment of risks of diazinon to the Kirtland's warbler	Kristina Garber,EPA; Nancy Golden, USFWS	SETAC 2015
Reducing pesticide exposure to threatened and endangered species	Scott Hecht, NMFS; Richard Marovich, California Department of Pesticide Regulation; Keith Paul, USFWS; Chuck Peck, EPA	SETAC 2015

Development of new tools to advance the estimation of pesticide exposure and effects for listed aquatic and terrestrial species.	Chuck Peck, EPA; Colleen Rossmeisl, EPA; Kristina Garber, EPA; Matt Etterson, EPA	American Chemical Society (ACS 2015), August, 2015
Selection and use of data in the assessment of pesticide risk to threatened and endangered species.	Nancy Golden, USFWS; Pat Shaw-Allen, NMFS; Kristina Garber, EPA	ACS 2015
Endangered Species Act Section (7) consultation in Federal land management agencies	Shawna Bautista US Forest Service, William P. Eckel, EPA; Thom Hooper, NMFS	ACS 2015
Development of generic aquatic habitats for estimating pesticide exposure in threatened and endangered species	Tony Hawkes, NMFS; Karen Myers, USFWS; Chuck Peck, EPA	ACS 2015
Aquatic modeling to estimate pesticide exposure to threatened and endangered species.	William P. Eckel, EPA; Chuck Peck, EPA; Cathy Laetz, NMFS; George Noguchi, USFWS	ACS 2015
The use of PUR data in a national-scale assessment: Interim measures for assessing the risk of pesticides to threatened and endangered species	Tony Hawkes, NMFS; Chuck Peck, EPA	Annual Meeting of the California Pesticide Use Report Analysis Workgroup, June, 2015

Applying an ecological risk assessment framework to national pesticide consultations: ESA definitions and practices	Scott Hecht, NMFS; Karen Myers, USFWS; Thom Hooper, NMFS; Patrice Ashfield, USFWS	SETAC 2014
Process for Determining Data Quality and Data Relevance for Pesticide Risk Assessments Conducted for Federally Listed Species	Melissa Panger, EPA	SETAC 2014
Using geospatial data to determine pesticide use areas for assessing the risk of national pesticide registrations to threatened and endangered species	Elizabeth Donovan, EPA; Jennifer Connolly, EPA; Steve Lennartz, EPA; James Cowles, EPA; Keith Paul, USFWS; Thom Hooper, NMFS	SETAC 2014
Using Generic Aquatic Habitats to Estimate Pesticide Exposure to Threatened and Endangered Species	Tony Hawkes, NMFS; Mark Corbin, EPA; Drew Crane, USFWS; Karen Myers, USFWS; Chuck Peck, EPA	SETAC 2014
Deriving protection thresholds for threatened and endangered species potentially exposed to pesticides	Matthew Etterson, EPA; Kristina Garber, EPA	SETAC 2014

Weighing lines of evidence to assess pesticide risk to threatened and endangered species	Scott Hecht, NMFS; Kristina Garber, EPA; Nancy Golden, USFWS; Wade Lehmann, EPA; David Baldwin, NMFS	SETAC 2014
Considerations for evaluating endangered species: A regulatory perspective	Scott Hecht, NMFS; Julann Spromberg, NMFS	ACS 2014